May 25, 2001

Kimberly Topper
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Opioid Analgesia use in Practice

Dear Ms. Topper:

I have been asked to express my views regarding the use of opioid analgesics in my practice. I am a physician specializing in Internal Medicine practicing in Eastern Connecticut. I am also the Medical Director of our local Hospice Program. I have extensive experience managing terminally ill patients, especially as regards to maximizing their comfort.

First of all, let me say, it would be nearly impossible to manage Hospice patients without the use of long-acting narcotic analgesics. The system we use is simple and works quite well. Basically, we will start a patient on long-acting narcotic analgesics in a dose that we think is appropriate to the patient's pain and overall condition. We also give short-acting narcotic analgesics for the patient to use for "breakthrough pain". If the patient ends up using a lot of breakthrough medicine, we know that our dose of long-acting analgesics is inadequate and we increase that dose. Once the patient stops using the breakthrough medicine, we know that analgesia is adequate. The short-acting medications are then left in reserve should the patient's underlying process worsen.

Long-acting narcotic analgesics are also extremely useful in the management of nonmalignant pain such as chronic low back pain and other musculoskeletal ailments. While modern medicine is generally pretty good at diagnosing and treating most conditions, there are still a fair number of patients who are dealing with pain of a sufficient severity to severely impact their lifestyle. Long-acting narcotic analgesics are extremely useful in turning these people to full functional capacity. Studies have shown that patients on stable doses of narcotic analgesics are able to drive, do mental calculation and function at a level much higher if they were allowed to experience severe pain. The risk of addiction in patients with both malignant and nonmalignant chronic pain is extremely low, generally less than 1%. Addiction is a psychological syndrome, whereby

the individual becomes obsessed with obtaining a euphoria from the medication. This euphoria becomes a central focus in the individual's life. In patients with chronic pain, pain relief rather than euphoria is the goal of treatment. While long-term use of narcotics do create a physical dependency, this is not equivalent to addiction. If patients use narcotics regularly and the narcotics are abruptly withdrawn, they will experience unpleasant physical side effects. This can be circumvented by slowly weaning the patient off narcotics should their pain improve. I hope this clarifies the difference between addiction and physical dependence. Another myth is that patients will require higher and higher doses of narcotics to get the same level of pain relief. This has also been shown not to be the case and patients generally do not require higher and higher doses of narcotics as long as they are underlying disease process remains stable. Should the disease worsen, such as we often see with cancer, the patients often require higher doses of narcotics. The other advantage of long-acting narcotics is that they are much easier to monitor. Once the patient is on a stable dose of long-acting narcotics, such as Oxy-Contin 80 mg bid, they are prescribed exactly that amount for one month's period of time.

In summary, I find these drugs invaluable in the treatment of both malignant and nonmalignant pain. Many negative myths exist about the use of narcotic analgesics and more education is needed so that these myths may be discounted and discredited.

Thank you for your attention to this important matter.

Sincerely,

Michael A. Kilgannon, M.D.

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